

### REMARKS

In reply to the Office Action mailed January 30, 2007, Applicants amended the abstract and claims 4 and 13. Claims 1-16 are pending and under examination. Please consider the following remarks.

Claim 13 was objected to under 27 DFR 1.75(c) as being in improper form. Applicants have amended claim 13 to remove the multiple dependencies. Therefore the objection should be withdrawn.

Claims 4-11 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Applicants amended claim 4 to delete the term "for available" in steps 4b and 4c, and replace this term with the term "for later use." Applicants submit that amended claim 4 is sufficiently definite and request that the corresponding rejection be withdrawn.

Applicants have discovered a novel medicine, which can be used in the treatment of ulcerative colitis. The pending claims are directed to a preparation of traditional Chinese medicinal materials for the treatment of ulcerative colitis, characterized in comprising the raw materials as 1-10 wt % of Sanguis Draxonis, 15-40 wt % of Radix Paeoniae Rubra, 1-20 wt % of Indigo Naturalis, 1-10 wt % of Halloysitum Rubrum, 15-40 wt % of Catechu, 1-10 wt % of Calcined Alumen, 5-30 wt % of Rhizoma Bletillae and 1-10 wt % of Calamina. The novel medicine provides for the treatment of ulcerative colitis with traditional materials generally effective in the treatment of "exterior sore." The claimed compositions therefore have the effect of removing the putrid tissues and promoting the tissue regeneration, thus "treating the exterior sore from within."

Claims 1-3, 12, and 14-16 were rejected under 35 U.S.C. 103(a) as being unpatentable over Yanaki et al. (US 5,538,728), Guo (CN 1051236 c), Song et al (CN 1202361 A), and Tao (US 6,383,524 B2). None of the cited references discloses the claimed combination of components, nor are they relied upon for such a disclosure.

Yanaki discloses a complex material of a hydrophilic polymer-silicate mineral that includes a carboxyl group containing hydrophilic polymer and a water swellable silicate mineral. (See Abstract.) The disclosed material has a plurality of uses, including cosmetics and pharmaceuticals. The Examiner relies on Yanaki for a disclosure of alumen (i.e., alumina),

paeniae (i.e., peony), and halloysitum (i.e., kaolin) (See Office Action, page 3.). While Yanaki discloses the use of the complex material as a laxative, nowhere does Yanaki disclose the three elements above combined in a laxative. Rather, the example of a laxative disclosed in Yanaki does not include a single of the three components above. Instead the laxative includes complex material, plantago•obata seed skin, parboxymethyl cellulose, sennoside, and bisbenthiamine.

Applicants submit that the Examiner's characterization of Yanaki to combine the three recited components is the result of improper hindsight, using Applicants' claimed invention as a road map. In fact, the only disclosure of halloysitum (i.e., kaolin) in Yanaki is as a component in a cosmetic such as a foundation (see Example 28) or a powder (see Example 44). Moreover, the only mention of paeniae (i.e., peony) is as a laundry list of components described as "other components conventionally used in pharmaceuticals, quasi-drugs, cosmetics, foods, agricultural medicines, etc." Nothing in Yanaki regarding either halloysitum (i.e., kaolin) or paeniae (i.e., peony) would lead one of skilled in the art to either use the components to treat ulcerative colitis or to use the components in a preparation of traditional Chinese medicine as claimed.

Guo is cited for disclosing hyacinth betallea and calamine to stop bleeding and pain of internal and external injuries. (See Office action, page 3.) Guo discloses a medicinal powder including traditional Chinese medicines with ophicalcite, tuber of hyacinth betilla, pseudo ginseng powder and calamine. (See Abstract.) Nothing in Guo suggests that hyacinth betallea and calamine would be effective to stop bleeding and pain without ophicalcite and pseudo ginseng powder or when combined with another component such as those recited in Applicants' pending claims.

Song is cited for the disclosure of natural indigo and catechu for inflammatory enteropathy (See Office Action, page 4.) Song discloses a Chinese medicine powder including natural indigo, Catechu, alumen, Cortex Phellodendri and pearl. (See Abstract.) Nothing in Song suggests that any of the components would work for disclosed purpose (i.e., treatment of inflammatory enteropathy) when taken outside of the disclosed combination. Therefore, Applicants submit that one skilled in the art, reading Song, would not have been lead to specifically identify a subset of the disclosed components and combine them, for example, with a different subset of components from another sited reference, for example, that of Guo, Tao, and Yanaki.

Tao discloses compositions and methods for enhancing the effects of therapeutic compositions. In some embodiments the compositions include sanguis draxonis (i.e., daemonorops or xuejie). Tao does not disclose a traditional Chinese medicine including the claimed combination of components, nor is Tao relied upon for such a teaching.

In determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983). Applicants submit that pending claims would not have been obvious in light of the cited references because nothing in the references would have led to the claimed combination of Applicant's invention, specifically a preparation of traditional Chinese medicinal materials including the recited components. Applicants submit that nothing in the references, when taken as a whole, would have led to the combination of components as recited in the pending claims. Applicants submit that instead, the Examiner has improperly used patentee's claim as a blueprint to reconstruct the claimed invention from the prior art. (See *Interconnect Planning Corp. v. Feil*, 774, F.2d, 1132.) In view of the foregoing, Applicants request that the above rejection be reconsidered and withdrawn.

Claims 4-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yanaki et al. (US 5,538,728), Guo (CN 1051236 c), Song et al (CN 1202361 A), Tao (US 6,383,524 B2), Shastri et al. (US 4,017,615), and Verge et al. (US 5,800,817). Claim 4 and those claims depending therefrom are directed to methods of preparing the traditional Chinese medicine claimed in claim 1. Applicants submit that the combination of Yanaki, Guo, Song, and Tao do not render obvious claims 4-13 for at least the reasons recited above regarding claims 1-3, 12, and 14-16.

Shastri is cited for the disclosure of polyethethylene glycol 400, tragacanth, and potassium sorbic acid for medical ointments. (See Office Action, page 6.) Shastri does not disclose the recited combination of components for a traditional Chinese medicine, nor is it relied upon for such a disclosure. Verge is cited for the disclosure of methods of processing plant material using various method. (See Office Action, the paragraph bridging pages 6 and 7.)

Verge does not disclose the recited combination of components for a traditional Chinese medicine, nor is it relied upon for such a disclosure.

Applicants submit that for at least the reasons above, the six cited references, when taken as a whole, do not fairly suggest the claimed invention, when taken as a whole, as required to maintain a prima facie case of obviousness. Applicants therefore submit that the corresponding rejection should be withdrawn. Applicants submit that the application is in condition for allowance, which action is requested.

Enclosed is a Petition for Three-Month Extension of time and the fee of \$1020 is being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply all charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 18200-002US1.

Respectfully submitted,

Date: July 30, 2007

/Catherine M. McCarty/

Catherine M. McCarty  
Reg. No. 54,301

Fish & Richardson P.C.  
225 Franklin Street  
Boston, MA 02110  
Telephone: (617) 542-5070  
Facsimile: (617) 542-8906